REMARKS

Claims 16-23 are pending. Claims 24-30 have been withdrawn pursuant to a restriction requirement.

Examiner Interview

Applicant Jason Gordon Beith and his Attorney Larry S. Zelson thank Examiner Jonathan R. Stroud and Primary Examiner Thomas J. Sweet for their time and consideration during the personal interview on Wednesday, March 25, 2009 at the U.S. Patent and Trademark Office. The interview is summarized herein, in accordance with MPEP § 713.04, by way of the following remarks and the 37 C.F.R. § 1.132 Declaration of Jason Gordon Beith ("Beith Declaration"), which is appended hereto.

In the interview, Applicant explained the state of the art prior to the current invention and the problems associated with prior art artificial heart valve leaflets, including the problem of lack of durability due to catastrophic leaflet failures. Applicant further explained how he was able to identify the previously unknown source of the problem in prior art valves by undertaking a dynamic analysis that was not previously undertaken (or even believed to be necessary) by any prior artisan having ordinary skill in the field, and how the insight Applicant gained into the source of the problem as a result of his dynamic analysis was instrumental in both predicting failures in prior art devices and designing the novel and nonobvious geometric shape and configuration of presently claimed invention.

At the conclusion of the interview, the Examiner suggested that Applicant file a response accompanied by a Declaration to enter into the record information discussed during the interview.

Amendments to the Drawings

Labels have been added to Figs. 2b, 4a, 4b, 5b, 7c, 7d, 8a, 8b, 8c, 8d, 11a, 11b, 11c, and 11d to indicate that the drawings refer to prior art.

A label has been added to Fig. 5c to indicate that the drawing refers to related art.

Rejection under 35 U.S.C. § 103(a)

Claims 16-23 stand rejected under 35 U.S.C. § 103(a) as unpatentable over US 2002/0082687 (Moe). Claims 17-23 depend from claim 16.

Claims 16-21:

As was discussed during the Interview of March 25, 2009, Applicant respectfully submits that claim 16, with particular reference to the features set forth in the fourth clause of claim 16, is novel and nonobvious over Moe and all other artificial heart valve leaflets in the prior art. In particular, the claimed valve leaflet has a shape that results in the mid-plane of the valve being substantially linear, as shown in Fig. 10 of the present application, such that the leaflet does not have a "belly" resulting from curvature in the axial direction. This aspect of the valve leaflet is recited most particularly in the fourth clause of claim 16, as follows:

> wherein the length of the leaflet between the lateral edges measured at any height (Z) along the lateral edges in an (XY) plane substantially perpendicular to the blood flow is defined by a parabolic function wherein the lengths determined by the parabolic function vary in a substantially linear fashion with the height (Z).

Moe Does Not Render Obvious the Claimed Valve Leaflet

In the Office Action, the Examiner contends that "Moe discloses a general method for creating leaflets of providing leaflets having geometries represented by analytic geometry." Applicant respectfully disagrees.

As the Examiner agreed during the Interview, analytical geometry is a tool that can be used to create an infinite number of shapes and combinations of shapes. Therefore, the mere fact that Moe used analytical geometry to determine the shapes of the valve disclosed therein adds nothing to the knowledge of one of ordinary skill in the art. Indeed, many other prior art valve designers also used analytic geometric shapes as the basis for valve leaflets, and Moe proposed his design because he found the others' valves to be deficient. See Moe at paragraph 0019 (stating that the disclosed valve "provides advantages not obtained from prior art analytical shapes").

Moe discloses only a very specific leaflet shape that is a combination of particular analytical geometric shapes: a right-handed helix and a left-handed helix at a top portion of the leaflet, and a cylinder at the bottom portion of the leaflet. See Moe at paragraphs 0019 and 0027 – 0031, and in Figs. 5-11. Additionally, Moe specifically points out the deficiencies of other attempts to use analytical geometric shapes in discussing the prior art designs of US 4,888,009 (having leaflets of a spherical section) and WO 98/32400 (having leaflets with a cylindrical section and a spherical coaption end). Moe further explains that "[c]ylindrical leaflets with revolted leaflet end sections, e.g., spheres and toroids" provide adequate solutions in only limited conditions. In other words, Moe teaches that all analytical geometry shapes are not equivalent and it takes more than routine experimentation to obtain the shape he used, which is drastically different from the claimed shape. See Beith Declaration at paragraph 14.

Moe Lacks Enabling Disclosure with Respect to the Claimed Leaflet

Moe, by merely mentioning the use of analytical geometry as a tool for describing the disclosed shape, and noting by way of background that "[a]n analytic shape may include a portion of a cylindrical surface, of an ellipsoid, of a paraboloid, or of another shape that can be defined mathematically," does not provide enabling disclosure with regard to the claimed shape (or any other shape that differs from the specific combination of analytic geometric shapes taught therein). See Moe at paragraph 0006. In setting forth an obviousness rejection, MPEP § 2141.01(II) requires a reference to have the same content as that used in setting forth an anticipation rejection per MPEP § 2121.01, and MPEP § 2121.01 requires that a reference contain enabling disclosure. "The disclosure in an asserted . . . reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation." *See Elan Pharmaceuticals v. Mayo Foundation*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531 (Fed. Cir. 1985).

One of ordinary skill could not have done so in this case. Accordingly, the mere naming of analytical geometry and a "paraboloid" is insufficient to enable one of ordinary skill in the art to produce Applicant's claimed valve leaflet without undue experimentation from among the virtually infinite shapes and sizes and combinations of shapes available in analytical geometry. In this vein, Applicant respectfully points out that the claimed valve leaflet shape is not simply a "parabola" but is a three-dimensional geometric shape that is described by a series of parabolic functions that vary in length in a substantially linear fashion with respect to the axial direction of the valve. It is at least in part this linear variation, and not solely that each XY plane of the inventive leaflet is described by a parabolic function, that represents a novel and nonobvious departure from the practice of those skilled in the prior art.

Moe Does Not Render the Claimed Leaflet Shape Obvious to Try

In the Office Action, the Examiner asserts that it would be "inherently obvious to try various sizes and shapes via any and all analytic geometry," and that because "[p]arabolas are very well-known shapes very similar to the shapes of previously-designed heart valves, . . . for one of ordinary skill in the art, it would simply require routine experimentation within known parameters to obtain applicant's design."

As discussed in the Interview, Applicant respectfully submits that the Examiner's assertion does not accurately reflect the law as set down in *KSR Int'l v. Teleflex*, 127 S.Ct. 1727 (2007) (expressing the view that it may be obvious to try each of "a finite number of identified, predictable solutions" or to take "creative steps that a person of ordinary skill in the art would employ," thus excluding the situation in which undue experimentation among infinite possibilities would be required without predictable solutions). Because the number of shapes and combinations that can be derived by analytic geometry are infinite, and because the results of trying variously shaped heart valve leaflets are unpredictable, a rejection cannot reasonably based on the notion that a person of skill in the art could try "any and all analytic geometry" until a successful geometry was stumbled upon. Indeed, one of ordinary skill could have experimented for years without exhausting any and all possible analytic geometry shapes and without arriving at the claimed invention. See Beith Declaration at paragraph 14 (describing unsuccessful trial and error attempts to design

artificial heart valve leaflets, and the problems with lack of repeatability and scalability even for attempts that initially appeared successful).

Even Moe acknowledges that far more than routine experimentation with known geometric shapes is required. Moe specifically explains that several prior art "analytical geometry shapes" do not work, and that "[t]radeoffs must be made . . . among various possible geometries." Moe at paragraph 0008. ("Attempts have been made to improve valve performance by fabricating leaflets comprising more than one analytical shape," for example in WO98/32400 with leaflets having a cylindrical section and a spherical coaption end. Moe at paragraph 0011. "U.S. Pat. No. 4,88,009 shows a prosthetic heart valve comprising leaflets of a spherical section, with no additional coaption surface." Moe at paragraph 0009. "Cylindrical leaflets with revolved leaflet end sections, e.g., spheres and toroids, produce adequate topological solutions for only a limited range of valve heights and gap areas." Moe at paragraph 0018.) Further, as discussed below, the conventional wisdom, as set forth by Moe, would discourage experimentation in the direction pursued by Applicant. Moe at paragraph 0018 ("[I]t is desirable to have a valve leaflet defined by an analytical shape that provides a smooth transition surface from the leaflet belly to the coaption area.").

Moe (and Conventional Wisdom) Teaches Away from Claimed Valve Leaflet

Moe expounds the conventional wisdom as the criteria by which artificial heart valve leaflets must be designed, and thus teaches away from Applicant's design. See MPEP § 2141.03(VI) (Prior Art Must be Considered in its Entirety, Including Disclosures that Teach Away from the Claims). In particular, Moe sets out a valve design that is intended to achieve those criteria where prior art valves have failed:

> [0012] General engineering experience with tissue and polymer heart valves have [sic] established a number of criteria for these valves, including:
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> [0013] 1) A coaption surface which extends from the triple point to the commissure.
>
> [0014] 2) A coaption surface which is tangent to the belly geometry at its bottom and nearly vertical at its top.
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> [0015] 3) A simple, singly curved belly.

> [0016] 4) A height short enough to fit into the natural anatomy.
>
> [0017] 5) A small gap area between leaflets to reduce regurgitation.
>
> [0018] . . . Given the limitations of existing leaflet geometries, it is desirable to have a valve leaflet defined by analytic shape that provides a smooth transition surface from the leaflet belly to the coaption area . . . . Analytical shapes suggested in the prior art have not achieved these goals.

As discussed in the Interview, Applicant followed a different path that was not constrained by the criteria of the conventional wisdom, and therefore Applicant achieved a different, nonobvious, and superior result. See Beith Declaration at paragraphs 5-10 (stating that Moe followed the governing criteria set out under the conventional wisdom in the art) and paragraphs 22-25 (explaining how Applicant's approach deviated in significant ways from the conventional wisdom). Indeed, no person of ordinary skill in the art would have pursued the direction pursued by Applicant in developing the claimed valve leaflet, and Applicant encountered tremendous resistance from those of ordinary skill, and those with entrenched interests, who wanted to adhere to the beaten path. See Beith Declaration at paragraphs 22-23. Accordingly, a person of ordinary skill would not have had a reasonable expectation of success by taking the approach taken by Applicant. MPEP § 2143.02; Beith Declaration at paragraphs 6-10.

The present application describes the teaching away of the prior art and explains that success was achieved in the claimed valve only by going against the conventional wisdom.

> [0198] Thus, the prior art teaches that leaflets of heart valves should have considerable excess material in the vertical axis Z, parallel to the blood flow to enable a suitable seal to be achieved at the free edge of the leaflet and to reduce the stress present in the leaflet during open and closing.
>
> [0201] Previous valve designs have been largely based on tissue valves and have not taken account of the different material properties of synthetic material, particularly synthetic polymer material.
>
> [0202] In contrast to previous designs and teaching concerning valve construction, which was driven by the supposed need to obtain a close fitting seal of the leaflets, particularly at the free edge, the leaflets of the valves of the present invention were designed to minimise the stress

> experienced by the leaflet during cycling between the open and closed position.

Thus, as compared with the prior art, the resultant shape of the valve is significantly different.

> [0215] The conventional design including a 'belly' portion was previously favoured as it was though to maximise sealing of the valve at the free edge and minise regurgitation.
>
> [0213] In Fig. 5b which is a sectional view along line 3-3 [of Fig. 2b] illustrating the closed position of a leaflet of a valve of the prior art, a 'belly' portion 40 exists in the mid portion of the leaflet. This 'belly' portion between the free edge of the central portion of the leaflet causes leaflets of the prior art to have a double curvature, a curve in the XY and a curve in the Z. Further, the 'belly' shape 40 causes leaflets of the prior art to be almost concave in shape when viewed in cross section along the vertical midplane of the leaflet.
>
> [0214] As shown in Fig. 5a, which is a sectional view of the valve of the present invention along line 3-3 as shown in Fig. 2a, no 'belly' is present in the leaflets and in the Z the leaflet in the closed position is substantially linear.

Changes in Shape are not Obvious with Respect to Moe

In the Office Action, the Examiner asserts that the differences between Moe and the claimed invention would have been obvious as a mere change of shape. As discussed at the Interview, a change in shape can only be obvious as a matter of choice by a person of ordinary skill in the art "absent persuasive evidence that a particular configuration [is] significant." See MPEP § 2144.04(IV)(B); *In re Daily*, 357 F.2d 669 (CCPA 1966). Here, Applicant has indisputably demonstrated that the claimed configuration and leaflet shape is highly significant, and even critical, to the viability of an artificial heart valve comprising a plurality of such leaflets. See "Applicant's Valve Leaflet Performs Dramatically Better" below and Beith Declaration at paragraphs 19-34 and 39-47. Additionally, Moe provides no teaching to enable one of ordinary skill in the art to even attempt to design a valve leaflet having the geometry of the claimed invention.

Optimization of Ranges is Not Relevant with Respect to Moe

In the Office Action, the Examiner asserts that the difference between Moe and the claimed invention would have been obvious as optimization of ranges through routine experimentation, wherein the general conditions of a claim are disclosed in the prior art, citing MPEP § 2144.05(II)(A) and *In re Aller*, 200 F.2d 454, 456 (CCPA 1955). Applicant respectfully submits that the rejection and this section of the MPEP are entirely inapplicable. As was discussed in detail at the interview, Moe's mere use of analytical geometry as a tool (to develop a valve leaflet shape based on widely accepted prior art criteria) indisputably does not disclose the "general conditions" of the claimed valve.

Moreover, it is readily apparent that this section of the MPEP has been applied by the Examiner entirely out of context because it relates to ranges, e.g., ranges of temperature or concentration. The notion of optimizing implies that the prior art has already defined the general contour of the invention and the applicant is determining values of parameters that work best within that general contour, which is simply not the case here. The first sentence of MPEP § 2144.05(II)(A) states: "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical." In contrast, Moe does not teach the general leaflet shape that can be described by a series of parabolas that vary substantially linearly in length, as claimed, and therefore there are no parameters or ranges that one of skill in the art could even attempt to optimize.

Applicant Discovered the Source of a Problem and Solved the Problem

Prior skilled artisans sought to design artificial heart valves having a geometry modeled after natural tissue valves, and operated under the assumption that the largest stresses on a valve leaflet occurred in the fully closed position. See Beith Declaration at paragraphs 6-7 and 13. Further, prior skilled artisans were intensely focused on coaption of the valve leaflets in the closed position, to prevent or minimize regurgitation. See Beith Declaration at paragraph 8. These criteria lead to prior art valves having low bellies to withstand the static stress of backpressure. See Beith Declaration at 9-10. Indeed, prior art such as WO 98/32400 suggest that an advantage of a leaflet with a belly is that the belly distributes stress in the leaflet when the valve is closed and downstream pressure is greater

than upstream pressure. See the present application at paragraph 0197. "Thus, the prior art teaches that leaflets of heart valves should have considerable excess material in the vertical axis Z, parallel to the blood flow to enable a suitable seal to be achieved at the free edge of the leaflet and to reduce the stress present in the leaflet during open and closing." See the present application at paragraph 0198. However, as discussed at the Interview and in the Beith Declaration, the prior art was wrong on this point.

It is well accepted that in addition to devising a novel and nonobvious solution, a "patentable invention may lie in the discovery of the source of a problem" that has not been previously determined by those of skill in the art. See MPEP § 2141.02(III). Applicant was the first to recognize that despite the advent of artificial materials having "suitable hydrodynamic properties, many valves constructed using [such materials] nevertheless fail during use, due to fatigue caused by the repeated stresses of cycling from a closed to an open position." See the present application at paragraph 0013 and Beith Declaration at paragraph 14. Thus, Applicant was the first (and still the only artisan in the field) to propose and conduct dynamic simulations of valve leaflets in order to pinpoint the stresses during opening and closing that cause the valve leaflet failures. See Beith Declaration at paragraphs 22-25.

Based on the Applicant's original dynamic simulation model, he was able to determine that "the belly in the [prior art valves] as shown in Fig. 5b create[s] increased stress in the belly region" which results in localized stress concentrations in the leaflet. See the present application at paragraphs 0208 and 0209. These stress concentrations are primarily in the form of bending stresses that result from the doubly curved leaflet belly that was widely accepted as necessary in an artificial heart valve leaflet. See the present application at paragraphs 0137 and 0216 – 0218 and in Fig 7d; see also Beith Declaration at paragraphs 35-39.

> [0216] [T]he double curvature, which comprises curvature in XY plane and in Z plane results in excess leaflet material at both the open and closed position which promotes the formation of a bubble or buckle 50 in the leaflet material (as shown in Fig. 11) during movement from a closed to open position.

The excess material can be seen most clearly by comparing Figs. 7d (showing the curved midplane of a prior art valve leaflet) with Fig. 7b (showing the substantially linear midplane of the claimed valve). See also Beith Declaration at Figs. A-7A, A-7B, and A-7C. As a result of an excessive amount of material in the prior art "belly" valve leaflets, tremendous stresses and thus strain energy releases are generated in the prior art valve leaflets. The Applicant's dynamic analysis has shown that "the stress in [leaflet belly area] is caused by the leaflets requiring to change the direction of their curvature during cycling." See the present application at paragraph 0238 through 0240.

> [0239] In particular, as shown in Fig. 11, on cycling from a closed to an open position a region lower than the free edge forms a bubble like formation or buckle 50 on the surface of the leaflet which is opposite in direction to the curvature of the surface of the rest of the leaflet.
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> [0240] On moving from the closed to open position, the bubble like formation 50 is forced to become inverted such that it projects in an opposite direction causing a whip like action in the leaflet 30. This whip like action promotes high stresses in the area lower than the free edge 32 of the leaflet, as shown in Figs. 8a, 8b, 8c and 8d.

Applicant's dynamic model was able to accurately predict the failure modes of a prior art valve, and in particular the defect propagation that would lead to catastrophic valve failure. See the present application at paragraph 0237 and Beith Declaration at paragraphs 25-30.

Equipped with his unique understanding of the dynamic operation of artificial heart valve leaflets and the causes of the stress concentrations that lead to leaflet failures, Applicant developed, and now claims, a valve leaflet that minimizes the stress experienced by the leaflet during cycling between the open and closed positions by minimizing the excess material of the leaflets. See the present application at paragraphs 0202, 0205, and 0243. As a result, the claimed leaflet minimizes localized stress concentrations and creates a more uniform stress across the leaflet. See the present application at paragraph 0209 and Beith Declaration at paragraphs 31-34. In particular, the claimed valve leaflet results in a decreased stress envelope across the entire face of the leaflet and minimizes the propagation of defects across the leaflet, largely as a result of there being less excess material and the absence of a belly in the leaflet. See the present application at paragraphs 0241 and 0242.

"On moving from the closed to open position a bubble like formation 50 is no longer created and thus a whip like action does not occur in the leaflet." See the present application at paragraph 0243.

Applicant's Claimed Valve Leaflet Performs Dramatically Better

Most importantly, the claimed valve leaflet shows dramatically improved durability and survival as compared with prior art valve leaflets. In the Office Action, the Examiner asserts that "Applicant's device does not in fact perform differently than the prior art device because the prior art discloses the entire range of geometries definable by analytic geometry." As discussed at the Interview and above in the section "Moe Lacks Enabling Disclosure with Respect to the Claimed Leaflet," and as supported by the Beith Declaration filed herewith, the prior art does not disclose "the entire range of geometries definable by analytic geometry" because that range is infinitely large and Moe discloses only one specific set of analytic geometric shapes. Therefore, the claimed valve leaflet shape is structurally different from anything disclosed in the prior art. Moreover, Applicant has conducted extensive testing to prove that the claimed structure does perform very differently than prior art valves such that the claimed valve leaflet represents a significant advance in the state of the art in artificial heart valves.

A comparative prior art valve and the presently claimed valve were tested under like conditions, both in a laboratory and as pre-clinical animal implants. In laboratory testing, the prior art valve exhibited a 15% failure rate after less than 50 million cycles, the equivalent of about 15 months of operation, and when these valve leaflets failed, they did so catastrophically. Beith Declaration at paragraph 39 and Figs. A-2, A-4. Further, the failures were exactly as predicted by Applicant's dynamic model. In animal testing, only 4 of 7 prior art valves survived for six months. Beith Declaration at paragraph 40. In addition, almost immediate failure could be caused by introducing small defects into the prior art valve leaflets. Beith Declaration at paragraph 45.

In contrast, 100% of the claimed valves in one test in excess of 400 million cycles (equivalent of over 10 years) and 100% of the claimed valves in another test achieved 420 million cycles (equivalent of 10-1/2 years). Also, 100% of tested valves in yet another test survived for 200 million cycles (equivalent of 5 years) at pressures much greater than those

ever generated by a healthy human heart. Beith Declaration at paragraph 41-42. In animal testing, all 15 implanted valves survived the six month test. Beith Declaration at paragraph 42. In addition, the claimed valve did not fail even when multiple defects were introduced into the leaflets. Beith Declaration at paragraph 45.

Unexpected Beneficial Results

As a result of not having to invert leaflet bellies each time the valve the claimed valve is moved from a closed to an open position, the claimed valve requires a substantially lower pressure gradient for opening than prior art valves. See the present application at Fig. 13 and paragraphs 0286-0287 (noting that the "23 mm" curve designates the "prior art" valve discussed throughout the application and the "23 mm new design" curve designates the claimed valve). As a result, the net positive flow through the claimed valve exceeds that through prior art valves. Beith Declaration at paragraphs 47-48.

Summary of Nonobvousness of Claims 16-21 over Moe

In sum, the state of the art prior to the inventive valve was based on a conventional approach used by those of skill in the art whereby artificial heart valves were designed to be shaped like natural tissue valves. The resultant valve geometries and configurations create stress problems in those valve leaflets and cause a lack of durability. In particular, the belly present in a natural tissue valve causes stress concentrations and releases of strain energy that lead to valve leaflet failure. Further, the focus on coaption surfaces turns out to be unnecessary since the claimed valve not only adequately prevents regurgitation, but allows a higher net throughput due to a lower opening pressure.

Applicant took a novel and nonobvious approach to developing the claimed valve, and persevered against resistance by those of ordinary skill in the art who would not have found his approach to be obvious, or even likely to be successful, in view of Moe. Prior to Applicant, no skilled artisan had done a dynamic analysis to look at strain energy density of valve leaflets; rather it was assumed that it was sufficient to evaluate only the static stresses in the fully opened and fully closed states. As discussed at the Interview, the methods of analysis used by Applicant are not trivial and required new software and computational resources that were not used or even considered necessary by prior art valve designers.

Applicant's approach was able to identify high stress regions that were causing the failure of prior art designs and to thereby determine a leaflet shape that would overcome the failure problems by avoiding such high stress regions. Even after Applicant was able to predict the failure modes of prior art valves, he still encountered resistance from those of ordinary skill in the art who dismissed this approach and said that it would not work because the geometry was different from what had been done in the prior art.

Ultimately, the claimed valve leaflet has a geometric shape that is novel and nonobvious over the prior art, including Moe. Those structural differences are captured in the claim language, as discussed specifically at the conclusion of the Interview. Moreover, the structural differences results in dramatic improvements in performance and durability compared with prior art valves.

Claims 17-21 depend from claim 16 are patentable over Moe for at least the same reasons as claim 16. Accordingly, Applicant respectfully request that the rejection of claims 16-21 be withdrawn.

Claims 22-23:

Claims 22-23 depend from claim 16 are patentable for at least the same reasons as claim 16. Further, because claim 22 has additional features that render it independently patentable over Moe, and because claim 23 depends from claim 22, those claims are discussed separately.

One region of stress concentration in prior art leaflet valves was determined to be near the center of the free edge of the valve, which caused propagation of defects generally perpendicular to the free edge and axially into the leaflet. Beith Declaration at paragraph 30; see also the present application at paragraph 0237 and Figs. 8a, 8b, and 8d. These stress concentrations are alleviated when the free edge of the leaflet is trimmed to have a parabolic shape, as recited in claim 22. See the present application at paragrapsh 0061-0062 and 0204-0204, and Figs. 9a, 9b, and 9d.

A person of ordinary skill in the art, with knowledge of Moe, would not have designed a valve having a parabolically shaped free edge as claimed, because such a curved free edge appears to be contrary to the stated goal in Moe and other prior art references of maximizing coaption, or surface contact near the free edges, of the valve leaflets in the

closed position. "[T]his design, contrary to previous teaching, does not necessarily allow close fitting to be achieved between the leaflets at all points along the free edge. However, surprisingly, the seal obtained between the leaflets using a parabolic or like function was found to be sufficient to minimise regurgitation of blood through the valve to the required degree for the valve to be effective." See the present application at paragraph 0204. Indeed, because the claimed valve has a lower opening pressure gradient, the net positive flow through the claimed valve exceeds that of prior art valves, even though the claimed valve may allow slightly more regurgitation when closed. Beith Declaration at paragraphs 47-48.

Therefore, both on their own merits and by virtue of their dependence from claim 16, claims 22 and 23 are patentable over Moe. Accordingly, Applicant respectfully requests that the rejection of claims 22 and 23 be withdrawn.

Conclusion

In sum, the prior art, as exemplified by Moe, taught a valve leaflet having a belly as being necessary for proper coaption and sealing, and for mimicking a natural tissue valve. Applicant determined what nobody of ordinary skill in the art had previously understood, i.e., that valve failures were due to repeated stress concentrations that occurred on every opening and closing and were caused by the buckling in and out of the belly that every skilled artisan at the time thought was required in a leaflet design. Applicant then designed the claimed valve leaflet, without a belly, using his understanding and knowledge that nobody of ordinary skill in the art had or could have had based on the prior art teachings, including Moe. In particular, the claimed valve has leaflets shaped without a belly: "wherein the length of the leaflet between the lateral edges measured at any height (Z) along the lateral edges in an (XY) plane substantially perpendicular to the blood flow is defined by a parabolic function wherein the lengths determined by the parabolic function vary in a substantially linear fashion with the height (Z)."

Most importantly, the claimed valve, with a nonobvious geometry that went against the conventional teachings, proved to have superior performance and durability, and can seal nearly as well as the prior art valves while lasting dramatically longer.

In view of the foregoing, Applicant respectfully submits all pending claims are in condition for allowance. Accordingly, withdrawal of the rejections, and an early notice of allowance of claims 16-23, is earnestly solicited.

Respectfully submitted,

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